Appendixes

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (1)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
Class III products	1. In all circumstances	Products have not been approved by the country of origin for sale in the home market.	Document of approval for clinical trial in China, clinical trial scheme and clinical trial report are required.
Class III implantables	2. Enterprises whose products have not been marketed in China	Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market.	Document of approval for clinical trial in China, clinical trial scheme and clinical trial report are required.
	3. Enterprises whose products are already in the Chinese market	A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, but the applied product is not manufactured under the same QS.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.

		B including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, and the applied product is manufactured under this QS within its term of validity; 3. Other products of the enterprise have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government origin for registration and sale is required.

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (2)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
Class III implantables	4. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of the same series yet not the same model.	**A.** Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, but the applied product is not manufactured under the same QS.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report of products of the same series issued upon approval for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
		A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, and the applied product is manufactured under this QS within its term of validity. 3. Products of the enterprise within the same series have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A.	As for domestic products, clinical report of products of the same series upon registration and sale is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required
	5. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of	A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report

	the same model yet not the same specifications.	the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, but the applied product is not manufactured under the same QS.	issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
		B. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. The Quality System of the enterprise has been inspected by the Chinese government, and the applied product is manufactured under this QS within its term of validity; 3. Products of the enterprise within the same series have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A.	As for domestic products, clinical report of products of the same series upon registration and sale is required; As for overseas products, clinical report of products of the same series issued upon approval by the government of origin for registration and sale is required.

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (3)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
Other class III products	6. Enterprises whose products have not been marketed in China	Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market;	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
	7. Enterprises whose products are already in the Chinese market; initial marketing of the applied products in the Chinese market.	A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. Products pertain to therapeutic device using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
		B. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. Products pertain to either diagnostic device or therapeutic device not using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles. 3. Other products of the enterprise have been marketed in China with no record of complaint for more than four years. Note: products with record of complaint shall be subject to the implementation of regulation A.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required.

Itemized Regulations on Clinical trial Report Concerning Registration of Medical Device (4)

Product Class	Preconditions	Qualifications	Requirements for the Submission of Clinical Report
Other class III products	8. Enterprises whose products are already in the Chinese market. The applied products and the registered products are of the same series.	A. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. Products pertain to therapeutic device using as its source of treatment ultrasound, laser, X-ray, gamma ray and other radioactive particles.	As for domestic products, the relevant clinical report is required; As for overseas products, clinical report issued upon approval by the government of origin for registration and sale is required. This report still waits to be approved by the specialist panel selected by the Chinese government.
		B. Including: 1. Domestic products have not been approved for sale; overseas products have been approved by the country of origin for sale in the home market; 2. Products of the same series by the enterprise have been marketed in China with no record of complaint for more than four years; 3. Products with record of complaint shall be subject to the implementation of regulation A.	Clinical report of products of the same series upon approval for registration and sale is required.
Class II products	1. In all circumstances;	Domestic products have not been approved by the Chinese government for sale; overseas products have not been approved by the country of origin for sale in the home market;	Document of approval for clinical trial in China, clinical trial scheme and clinical trial report are required.
	2. Initial marketing of the products in the Chinese market.	A: Overseas products have been approved by the country of origin for sale in the home market.	Clinical report issued upon approval by the government of origin for sale is required.

		B: Domestic products of the same series have been approved by the Chinese government for sale in the home market and have been on sale for more than two years.	Clinical report of products of the same series upon approval for registration and sale is required.

Notes:

2. The term *products of the same series* refers to products sharing the same basic principles, major functions and structure;

3. The term *products of the same model* refers to products of the same principle and structure in terms of supplementary functions, while they share the same basic principles, major functions and structure;

4. The term *products of the same specifications* refers to products of the same parameters and indexes in terms of major functions, while they share the same basic principles, major functions, structure as well as the same principle and structure in terms of supplementary functions;

5. The term *complaint* refers to cases accepted by the drug administrations at state, provincial and municipal levels and decided by technical method to have been caused by problems concerning product quality;

5. The term *products* in this chart refers all to edical device